Notice of Allowability	Application No.	Applicant(s)	
	09/724,985	SAVAGE, PHILIP MICHAEL	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *papers filed 11/17/2006*.

2. ☒ The allowed claim(s) is/are *1,3,4,9,12-14,16,17,26,27,29,37,46-48,50-52,56,57,60,63,67,68,75 and 76*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20070201* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Angela Collison on February 1, 2007.

The application has been amended as follows:

IN THE CLAIMS:

Claims 11, 15, 18-25, 28, 30-36, 38-45, 53-55, 58-59, 61-62, 64-66, and 69-74 are canceled herewith.

The **following claims are amended** with ~~strikethrough~~ or [[double bracketing]] indicating deletion of an element and underlining indicating addition:

1. (Currently Amended) A complex comprising an HLA class I molecule or fragment thereof having a peptide binding groove, the HLA class I molecule or fragment thereof comprising[[:]] a T cell ~~binding~~ recognition portion, and an ~~attaching~~ attachment means for selectively attaching said HLA class I molecule or fragment thereof to a target cell, wherein the HLA class I molecule or fragment thereof is bound or is attached to a recognition peptide in the peptide binding groove of the HLA class I molecule or fragment thereof, wherein the recognition peptide is arranged to be presented by said HLA class I molecule or fragment thereof for T cell recognition, wherein the attachment means comprises:

a) a linking polypeptide with specific affinity for a molecule on the surface of the target cell; and

b) a coupling system for coupling the linking polypeptide to the HLA class I molecule or fragment thereof, wherein the coupling system comprises:

(i) a first small molecule joined to the linking polypeptide; and

(ii) a second small molecule joined to the HLA class I molecule,

wherein the first and second small molecules are each selected from biotin and avidin/streptavidin or calmodulin and calmodulin binding peptides;

wherein interaction of the small molecules forms a stable bridge between the linking polypeptide and the HLA class I molecule.

4. (Currently Amended) A complex comprising an HLA class I molecule or fragment thereof having a peptide binding groove, the HLA class I molecule or fragment thereof comprising[[:]] a T cell ~~binding~~ recognition portion, and an ~~attaching~~ attachment means for selectively attaching said HLA class I molecule or fragment thereof to a target cell, wherein said ~~attaching~~ attachment means comprises a linking polypeptide which is bound or is attached to said target cell and wherein said linking polypeptide is ~~adapted to be~~ attached directly to said HLA class I molecule or fragment thereof; and wherein the HLA class I molecule or fragment thereof additionally is bound or is attached to a recognition peptide in the peptide binding groove of the HLA class I molecule or fragment thereof, wherein the recognition peptide is arranged to be presented by said HLA class I molecule or fragment thereof for T cell recognition.

9. (Currently Amended) The complex as claimed in claim 1, which complex comprises:

(i) ~~a recombinant protein, which recombinant protein includes~~ a moiety comprising a recombinant protein that includes said HLA class I molecule or fragment thereof, and

(ii) a moiety comprising said ~~attaching~~ attachment means.

14. (Currently Amended) The complex as claimed in claim 1, wherein the allotype of said HLA class I molecule or fragment thereof is different from the allotype of the HLA class I molecules of ~~the patient~~ a subject, so that an alloreactive response can additionally or alternatively be triggered against said target cell.

16. (Currently Amended) A complex as claimed in claim ~~15~~ 1, wherein ~~there is a~~ the recognition peptide ~~that~~ comprises a tumour specific peptide, or a viral peptide, or a bacterial peptide, or a parasite peptide, or any peptide which is ~~exclusively or characteristically~~ presented by HLA class I molecules on the surface of diseased or malignant cells, or virally, bacterially, parasitically or microbially infected cells, or foreign cells~~, the presence of which is undesirable in a patient~~.

26. (Currently Amended) A ~~pharmaceutical~~ composition ~~for treating a patient having a disease or condition characterised by the presence of diseased, foreign or malignant cells in the body of the patient, said pharmaceutical composition~~ comprising a complex as claimed in claim ~~11~~ 1 and an appropriate excipient or carrier.

27. (Currently Amended) A method of preparing ~~the pharmaceutical~~ a composition comprising a target cell, a complex as claimed in claim 1 and an appropriate excipient or carrier ~~of claim 26~~ comprising providing a target cell, ~~producing~~ selectively attaching the complex of claim ~~11~~ 1 ~~by selectively attaching an HLA class I molecule or fragment thereof~~ to the target cell, and addition of said ~~combining the complex of claim 11 with an~~ excipient or carrier.

29. (Currently Amended) A ~~pharmaceutical~~ pack or kit comprising one or more containers, each container having therein a ~~pharmaceutical~~ composition as claimed in claim 26, and written instructions for the ~~administration~~ use of said composition ~~to a patient~~.

46. (Currently Amended) A complex comprising an HLA class I molecule or fragment thereof having a peptide binding groove, the HLA class I molecule or fragment thereof comprising[[:]] a T cell ~~binding~~ recognition portion, and an ~~attaching~~ attachment means for selectively attaching said HLA class I molecule or fragment thereof to a target cell, wherein the HLA class I molecule or fragment thereof is bound or is attached to a recognition peptide in the peptide binding groove of the HLA class I molecule or fragment thereof, wherein the recognition peptide is arranged to be presented by said HLA class I molecule or fragment thereof for T cell recognition, wherein the attachment means comprises:

a) a linking polypeptide with specific affinity for a molecule on the surface of the target cell; and

b) a coupling system for coupling the linking polypeptide to the HLA class I molecule or fragment thereof, wherein the coupling system consists essentially of:

(i) a first small molecule joined to the linking polypeptide; and

(ii) a second small molecule joined to the HLA class I molecule,

wherein the first and second small molecules are each selected from biotin and avidin/streptavidin or calmodulin and calmodulin binding peptides;

wherein interaction of the small molecules forms a stable bridge between the linking polypeptide and the HLA class I molecule.

50. (Currently Amended) A complex comprising an HLA class I molecule or fragment thereof having a peptide binding groove, the HLA class I molecule or fragment thereof comprising[[:]] a T cell ~~binding~~ recognition portion, and an ~~attaching~~ attachment means for selectively attaching said HLA class I molecule or fragment thereof to a target cell, wherein the HLA class I molecule or fragment

thereof is bound or is attached to a recognition peptide in the peptide binding groove of the HLA class I molecule or fragment thereof, wherein the recognition peptide is arranged to be presented by said HLA class I molecule or fragment thereof for T cell recognition, wherein the attachment means comprises:

a) a linking polypeptide with specific affinity for a molecule on the surface of the target cell; and

b) a coupling system for coupling the linking polypeptide to the HLA class I molecule or fragment thereof, wherein the coupling system consists essentially of:

(i) a first small molecule joined to the linking polypeptide; and

(ii) a second small molecule joined to the HLA class I molecule,

wherein interaction of the small molecules forms a stable bridge between the linking polypeptide and the HLA class I molecule and wherein said coupling system consists of biotin and avidin/streptavidin.

51. (Currently Amended) A complex comprising an HLA class I molecule or fragment thereof having a peptide binding groove, the HLA class I molecule or fragment thereof comprising[[:]] a T cell ~~binding~~ recognition portion, and an ~~attaching~~ attachment means for selectively attaching said HLA class I molecule or fragment thereof to a target cell, wherein the HLA class I molecule or fragment thereof is bound or is attached to a recognition peptide in the peptide binding groove of the HLA class I molecule or fragment thereof, wherein the recognition peptide is arranged to be presented by said HLA class I molecule or fragment thereof for T cell recognition, wherein the attachment means comprises:

a.) a linking polypeptide with specific affinity for a molecule on the surface of the target cell; and

b.) a coupling system for coupling the linking polypeptide to the HLA class I molecule or fragment thereof, wherein the coupling system consists essentially of:

(i) a first small molecule joined to the linking polypeptide; and

(ii) a second small molecule joined to the HLA class I molecule,

wherein interaction of the small molecules forms a stable bridge between the linking polypeptide and the HLA class I molecule and wherein said coupling system consists of calmodulin and calmodulin binding peptide.

52. (Currently Amended) The complex as claimed in claim 46, which complex comprises:

~~(i) a recombinant protein, which recombinant protein includes~~ a moiety comprising a recombinant protein that include said HLA class I molecule or fragment thereof,

(ii) and a moiety comprising said ~~attaching~~ attachment means.

60. (Currently Amended) The complex as claimed in claim 46, wherein the allotype of said HLA class I molecule or fragment thereof is different from the allotype of the HLA class I molecules of ~~the patient~~ a subject, so that an alloreactive response can additionally or alternatively be triggered against said target cell.

67. (Currently Amended) A ~~pharmaceutical~~ composition ~~for treating a patient having a disease or condition characterised by the presence of diseased, foreign or malignant cells in the body of the patient, said pharmaceutical composition~~ comprising a complex as claimed in claim ~~53~~ 46 and an appropriate excipient or carrier.

68. (Currently Amended) A method of preparing a ~~pharmaceutical~~ composition ~~for treating a patient having a disease or condition characterised by the presence of diseased, foreign or malignant cells in the body of the patient, said pharmaceutical composition~~ comprising target cell, a complex as claimed in claim ~~53~~ 46 and an appropriate excipient or carrier comprising providing a target cell, ~~producing~~ selectively attaching the complex of claim ~~53~~ 46 ~~by selectively attaching an HLA class I molecule or fragment thereof~~ to the target cell, and addition of said ~~combining the complex of claim 53 with an~~ excipient or carrier.

75. (Currently Amended) A ~~pharmaceutical~~ pack or kit comprising one or more containers, each container having therein a ~~pharmaceutical~~ composition as claimed in claim ~~69~~ 67, and written instructions for the ~~administration~~ use of said composition ~~to a patient~~.

The **following new claim has been added** and does not introduce new matter:

76. (New) The complex of claim 1 wherein the target cell is a B cell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 1, 2007

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600